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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------------|------------------|
| 10/612,318      | 07/01/2003  | Sylvia G. Kachalsky  | 2094/0878/67656-A/JPW/FHB | 4833             |

7590

01/04/2006

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| EXAMINER |
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TURNER, SHARON L

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| ART UNIT | PAPER NUMBER |
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1649

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/612,318

Applicant(s)

KACHALSKY ET AL.

Examiner

Sharon L. Turner

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

1. Claims 1-23 are pending.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-2, 4, 8-9, 11 in part drawn to nucleic acids of SEQ IDNO:1, classified for example in class 536, subclass 23.1.
  - II. Claim 1, 3, 5, 8-9, 12 in part drawn to a nucleic acids of SEQ IDNO:3, classified for example in class 536, subclass 23.1.
  - III. Claim 6, 13-14,16, 18-19 drawn to the polypeptide of SEQ ID NO:2, classified for example in class 530, subclass 350.
  - IV. Claim 7, 13, 15, 17-19 drawn to the polypeptide of SEQ ID NO:4, classified for example in class 530, subclass 350.
  - V. Claims 10 in part drawn to an antisense molecule, classified for example in class 536, subclass 24.5.
  - VI. Claims 20-23 in part drawn to an antibody, classified for example in class 530, subclass 387.1.
3. Furthermore, in addition to the election of one of the above VIII groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group:
  - A) A single designated nucleic acid composition selected from SEQ ID Nos: 1 or 3.
  - B) A single polypeptide selected from SEQ ID NO:2 or 4.

C) A single antibody selected from reactivity with SEQ ID NO:2 or 4.

4. The inventions are distinct, each from the other because of the following reasons:

5. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated as A-C constitute patentably distinct inventions for the following reasons. Each of the antibodies, polynucleotides and polypeptides has a unique structural feature which requires a unique search of the prior art. The inventions indicated as A-C differ in structure and function as they are composed of divergent nucleic and amino acids and are differentially able to hybridize, bind or mediate biological functions. A reference to one element would not constitute a reference to another. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

6. Inventions I-VI are related as products. The products are distinct each from the other as the products are comprised of divergent structure and exhibit different effects and function, for example nucleic acids, antibodies, and peptides and each of the molecules has different structure and function.

7. Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together as each has

Art Unit: 1649

different structure and each is capable of different function.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as indicated is proper.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-VI and a single molecular embodiment for each of designated groups A-C to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that neither I-VI nor A-C are species election requirements; rather each of I-VI and A-C are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups. It is noted that while one of A-C may not be applicable to one of I-VI, applicant must elect one of each in order to be fully compliant.

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found

allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent

issues. See MPEP § 804.01.


13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.  
December 27, 2005

  
SHARON TURNER, PH.D.  
PRIMARY EXAMINER  
12-27-05